Ministry of Health

Ontario

Common Privacy Framework

Consent Management Implementation Guide

CCIM Assessment Projects

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CCIM Community Care Information Management

Sensitivity: Unclassified

This document has a CCIM Low Sensitivity Classification.

Table of Contents

NOTE: All terms that appear in the attached Glossary are underlined in this document.

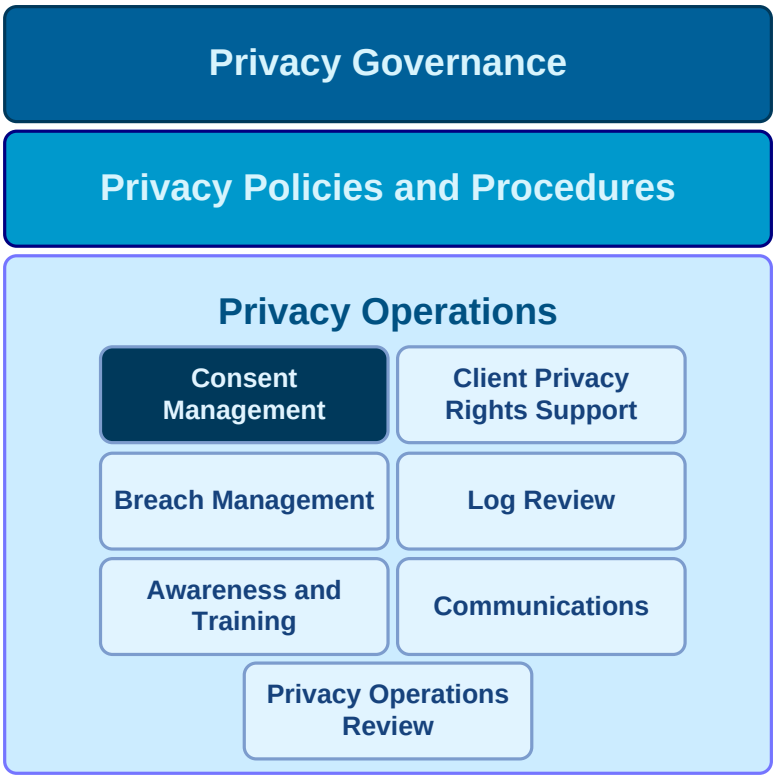
1. Introduction

This introduction describes the content of this Implementation Guide as well as the approach to Consent management used in the *Common Privacy Framework (CPF)*.

The Common Privacy Framework (CPF) was developed by Community Care Information Management (CCIM) to establish a baseline for Privacy practices among community care health service providers (HSPs) in Ontario in order to address the Privacy concerns of HSPs and their clients. In this context, *Privacy* describes the control clients have over their own personal health information (PHI) and how it is collected, used and disclosed by HSPs.

The CPF describes a broad range of Privacy concepts, including Privacy governance, policy, procedure and operations as outlined in the following framework diagram:

Figure 1: The Common Privacy Framework



The CPF supports the implementation of assessment projects throughout the community care sector in compliance with the *Personal Health Information Protection Act* (PHIPA). To help you do this, the CPF provides a toolkit composed of implementation guides for each of the Common Privacy Framework components listed in the diagram above. This Consent Management Implementation Guide is part of the CPF toolkit.

Note: CCIM is mandated to support implementation of common assessments across community care sectors in Ontario. As such, the CPF and its various toolkits were developed to ensure minimum Privacy standards for use and sharing of assessments. The CPF and its toolkits are based on PHIPA and represent good privacy practice. HSPs may consider whether these tools also support Privacy in other business processes and information management. If so, HSPs are encouraged to expand the use of the CPF accordingly.

1.1 About the Consent Management Implementation Guide

As part of the *Common Privacy Framework* (CPF)[1], this Guide provides the tools required to assist health service providers (HSPs) in augmenting their existing Consent management practices where needed in order to support PHIPA compliance when sharing assessment data. The Consent Management Implementation Guide is intended for HSPs involved in the implementation of Community Care Information Management (CCIM) assessment projects. This guide assumes readers have a basic understanding of Privacy. If you have questions regarding this toolkit, please contact the CCIM support centre at ccim@ccim.on.ca.

1.2 How to Use This Document

This document contains a step-by-step approach along with tools to help you develop and implement an effective Consent management process.

Section 2 – *Implementing a Consent Management Process* – This section describes the key decisions required to define or enhance your HSP's existing Consent management process. It also outlines the suggested steps and tools for developing and/or refining the process accordingly.

Section 3 – *Process Analysis and Design Worksheet* – This worksheet can be used to determine how closely aligned your HSP's current Consent management practices are to those outlined in the CPF. The Worksheet will also help you clarify what changes to your practices, if any, are necessary to align with the CPF.

Readers are encouraged to use the Process Analysis and Design Worksheet to review their Privacy processes and organize their planning. The Worksheet may also be an effective change-management tool - especially if it is used to engage colleagues in business review and design. You should also encourage the participation of the direct service and senior management as appropriate. With their input, current state descriptions should be more complete and new approaches easier to communicate and to implement.

Section 4 – *Samples and Templates* – Here you will find samples and templates to support a complete Consent management process including forms, brochures and posters. You are encouraged to customize these and use them to meet your HSP's unique needs.

The appendix to the this Guide contains additional information about the legal requirements for Consent as well as the pertinent parts of the Common Privacy Framework for your reference.

1.3 Consent Management Definition and Methodology

Consent management gives clients appropriate control over their Personal Health Information (PHI) and how it is collected, used and shared. In Ontario, many health service providers (HSPs) are required to manage PHI in

[1] For more details on the Common Privacy Framework, see the document at: www.ccim.on.ca

accordance with the *Personal Health Information Protection Act* (PHIPA). Implementing a clear and comprehensive *Consent management* process is essential to complying with PHIPA.

Consent management involves a consistent and thorough approach to respecting a client's Privacy preferences. An HSP often collects, uses and discloses PHI solely for the purpose of providing health care. A client may agree to an HSP's sharing his or her PHI, or may have specific preferences with respect to disclosure .

If a client gives particular instructions (i.e. provides a Consent Directive describing their preferred restrictions on the use or disclosure of his or her information), the HSP must ensure that these preferences are respected across all operational settings. This may require the use of administrative controls, like noting directives on paper charts or technical controls, such as applying Consent flags in electronic systems. One or both approaches may be an option, depending on the HSP's technological capability. Either way, Consent management processes have to be integrated into intake, triage, assessment, ongoing support and/or admission/discharge in order to ensure systematic protection.

Consent management is an essential element of the *Common Privacy Framework*. The CPF also describes a number of additional mechanisms for Privacy protection, including Log Review and breach management procedures. These elements complement and support Consent management. For instance, breach management can mitigate and contain events that violate a client's Consent Directives or expectations.

1.4 Background to Consent Management in the CPF

In 2010, as part of the *Common Privacy Framework* initiative, CCIM gathered information about Privacy practices from a variety of health service providers (HSPs). The participating HSPs provided CCIM with considerable input. In particular they described the key challenges faced with respect to Consent management. These include:

- Ensuring that clients understand their rights and obligations when giving PHI Consent
- Finding a means of keeping clients informed
- Accomodating varying Consent management practices across HSPs and programs
- Managing Consent Directives when technology to do so is not available

These and other insights were incorporated into a report entited *Current Privacy Practices of Community Care Health Service Providers*.[2]

[2] For more details on the research, see the final report at: www.ccim.on.ca

CCIM has since identified several approaches to addressing these Consent management challenges including this implementation guide. These approaches:

- Support Informed Consent
- Are flexible and accommodate implied Consent, express Consent or a mix of the two where appropriate
- Address the management and communication of Consent Directives
- Support both the use of electronic and non-electronic means to manage Consent
- Address the full timeline of the Consent Directive from when it is first collected, to how it is maintained or updated, and how it is archived and stored

2. Implementing a Consent Management Process

This section provides a step-by-step guide and introduces the supporting tools for refining, or developing and implementing a Consent management process that aligns with the Common Privacy Framework.

2.1 Consent Management Decisions

Developing a new or revised Consent management process requires a systematic approach. A health service provider (HSP) must choose a means of obtaining and respecting client Consent Directives while minimizing the impact on health service provision.

To begin, an HSP should make some important decisions to define its unique implementation requirements. Once these decisions are made, processes and supporting materials can be developed accordingly.

The key decisions for defining an effective Consent management process are:

1. How to inform the client/patient with respect to Consent
2. What type of Consent type to use (i.e., implied or express or some combination)
3. How to obtain the Consent or Consent Directive (i.e. Do you assume implied Consent or do you use a form to collect Consent?)
4. How to record Consent Directives
5. How to register (or update) Consent Directives
6. How to enforce Consent Directives (i.e., appropriate safeguards)
7. How to implement the Consent management process

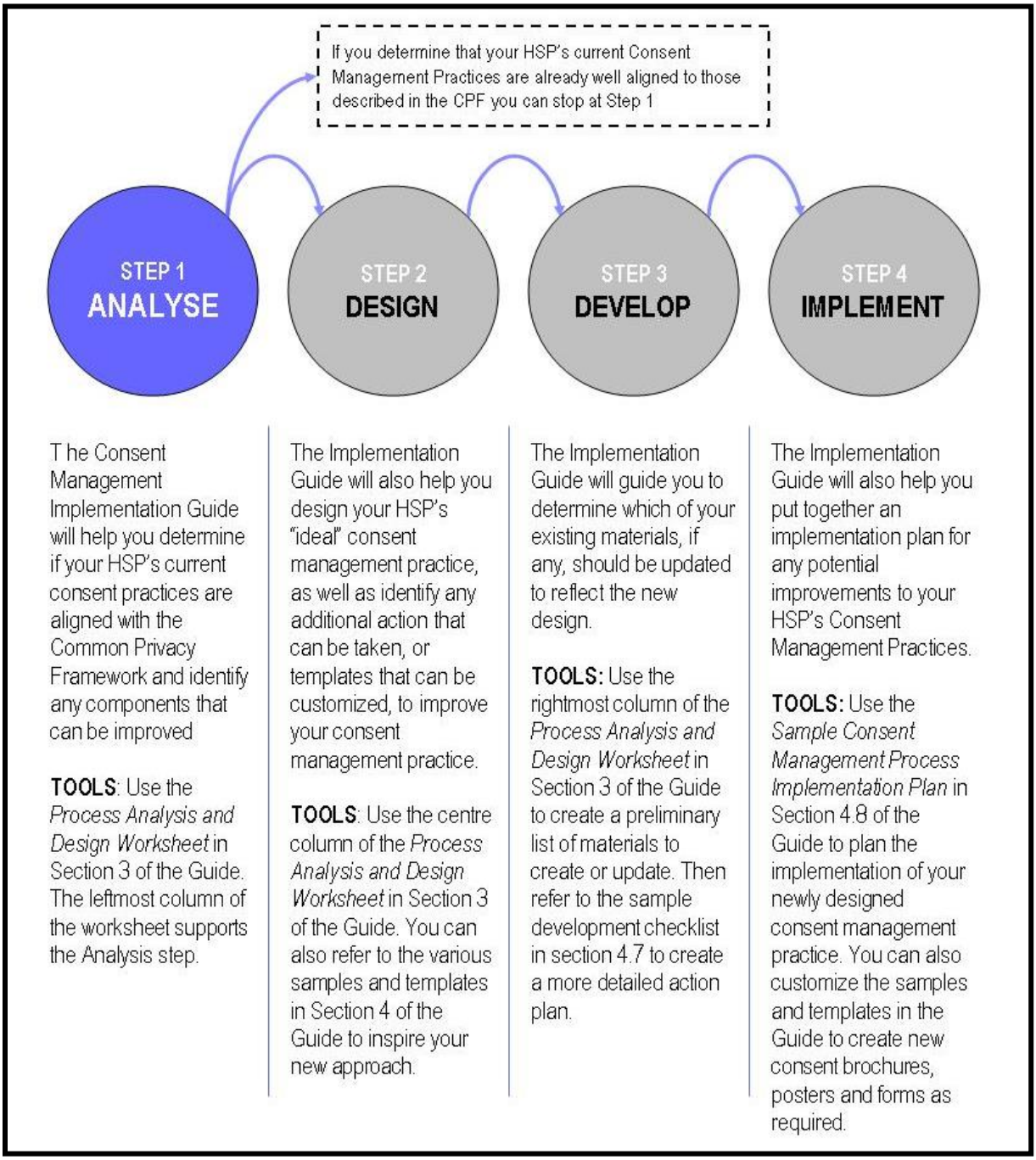
The *Process Analysis and Design Worksheet* included in section 3 of this Guide is based on these seven key considerations.

Note: while Privacy Policy is outside the scope of this Consent Toolkit, HSPs may find that their 'answers' to the above questions form a solid and appropriate outline to such policy.

2.2 Implementation Steps

This following diagram describes a four-step approach to the development and implementation of a Consent management process aligned with the Common Privacy Framework (CPF). All four steps are supported by this implementation guide's *Process Analysis and Design Worksheet* in section 3. See the following diagram for details:

Figure 2: *Four steps to implementing Consent Management*



3. Process Analysis and Design Worksheet

3.1 Purpose

As outlined in the last section, the attached Process Analysis and Design Worksheet can be used in all four steps of Consent management implementation to evaluate your health service provider's (HSP's) existing Consent management practices and enhance them if necessary.

3.2 How to use the Worksheet

Click here to access a version of the worksheet that you can fill out to support your analysis.

Click here to access a version of the worksheet with sample answers.

Engaging all staff involved in the organization's Privacy processes may be an effective way to use the Worksheet in completing the four steps described below, as well as ensuring any process changes are implemented effectively.

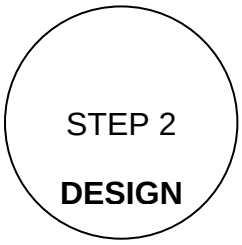
Use the Worksheet to determine how closely aligned your HSP's current Consent management process is to the Common Privacy Framework (CPF).

Begin working with the first column on each page of the Worksheet. Review the highlighted question on each of the nine pages. Each represents one Consent management requirement[3] from the CPF. Answer the question with either:

-
- "Yes as is"
- "Yes but needs improvement"; or
- "No/Don't Know."

Mark your answer and then move to the next question. When you have finished answering all the highlighted questions in the first column throughout the Worksheet, check to see whether all your answers are "Yes as is". If this is the case, your HSP is fully in line with CPF Consent management and you do not need to proceed to Step 2.

Use the Worksheet to design a new or refined Consent management process.



For any highlighted question to which you did not answer "Yes as is" in Step 1, read through the explanation in the first column and follow the instructions under "Yes but needs improvement" and "No/Don't know" to do the following:

- Document the pertinent aspects of your HSP's current practice in column 2 of the Worksheet
- Create a new or refined practice in column 3 of the Worksheet

[3] See full CPF requirements in Section 6

STEP 3

DEVELOP

Use the Worksheet to plan and then take action on your new or refined Consent management process.

Consider the difference between your health service provider's (HSP's) current Privacy practice in the second column of the Worksheet and the new one you've designed in column. Create an action plan to address these differences and write it up in last column.

STEP 4

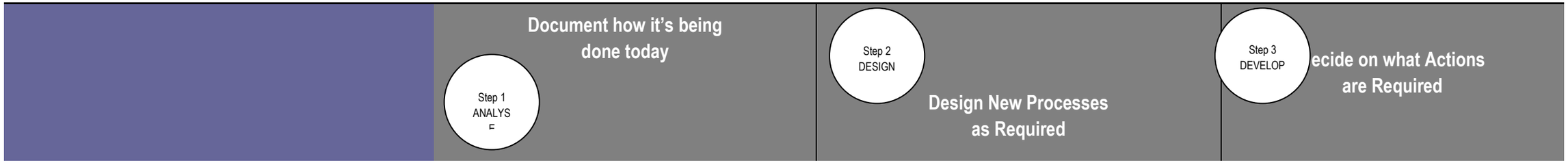
IMPLEME

The last section of the Worksheet entitled *Implementing a Consent Management Process* also suggests the training and other staff supports that are key to ijmplementing your new or refined plans. You can also use the *Sample Consent Management Process Implementation Plan* in Section 4.8 of the Guide to plan the implementation of your newly designed Consent management practice. You can also customize the samples and templates in the Guide to create new Consent brochures, posters and forms as required.

Note that a sample of the Process Analysis and Design Worksheet is provided with example responses in each section.

NOTE: The reference number (Ref. #) at the bottom of the first column of the Worksheet links to an activity/step in the *Sample Consent Management Processes* (Section 4.1). This link may help clarify the context of each question in the Worksheet.

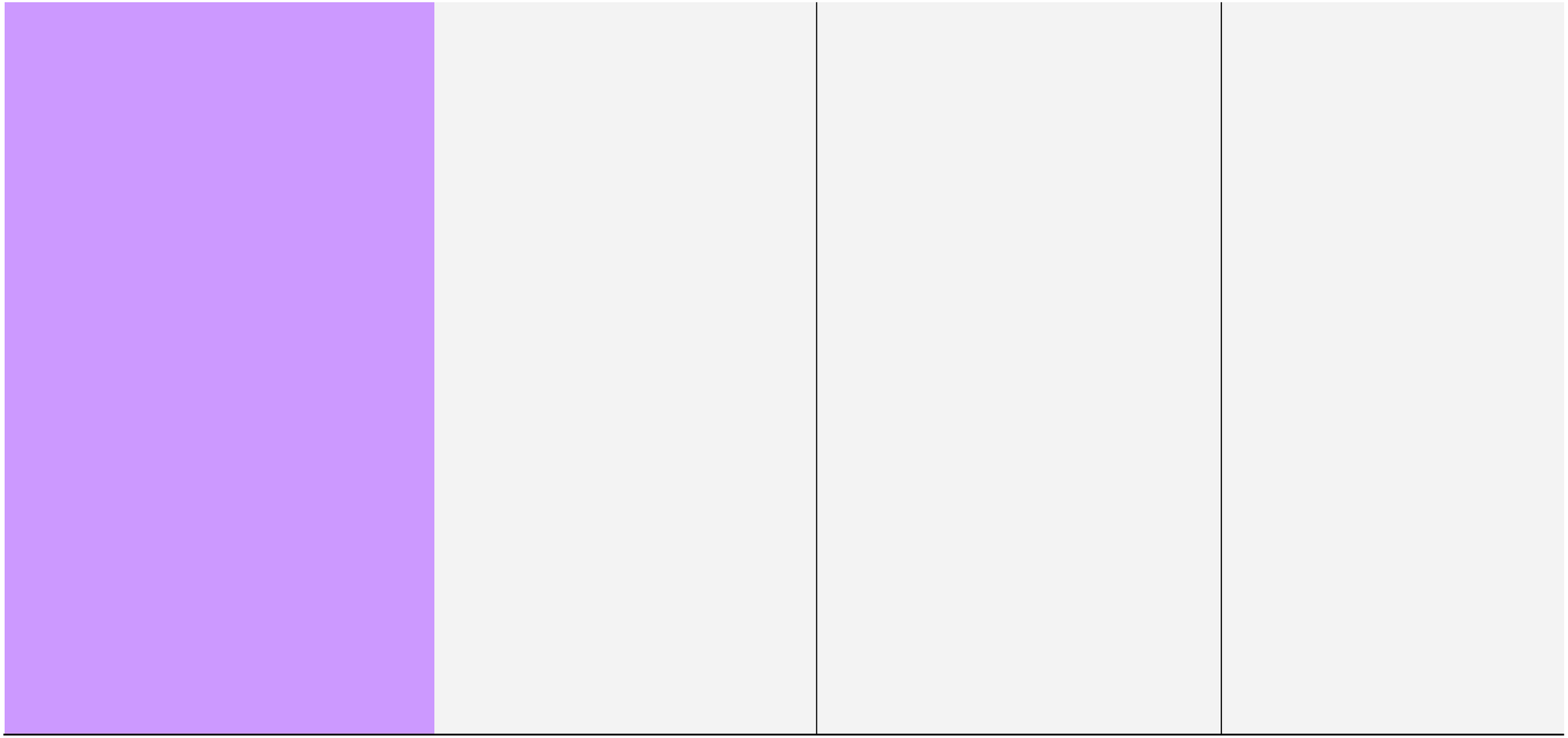
ANALYSIS AND DESIGN WORKSHEET



INFORMING THE CLIENT: HSPs will support Informed Consent. That is prior to Consent, clients will be clearly informed of: – what PHI will be collected, used and disclosed; – how PHI will be collected, used and disclosed; – that PHI may be disclosed to other HSPs; and – for what purpose will PHI be collected used and disclosed. In addition clients will be informed of their Privacy Rights and the positive or negative consequences of giving, withholding or withdrawing Consent. **Are clients clearly and fully Informed prior to their giving consent for PHI collection, use and disclosure?** ☐ **Yes as is:** Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** **If you answered either "Yes – but needs improvement" or "No/Don't know":** Informed Consent requires HSPs to make all reasonable	Use the space below (or a separate sheet) to describe all the means by which your HSP currently informs clients. Perhaps list all the ways in which clients interact with your HSP (e.g. web, phone, in person, etc). Consider when, how and what information is communicated to the client at each point in the assessment process.	Design a new approach to informing clients. Review the sample Poster, Brochure, Web Statement and Scripts provided in (ref 4.3). Would customizing and using any of these provide additional support to Informed Consent? Describe the new approach to informing clients, and any additional artefacts in the column below.	Consider the difference between the existing approach to informing clients and the new design. What tasks, steps and forms may be required? Document these in the Action Plan column below.

efforts - prior to Consent to ensure clients understand their Privacy rights along with the what, why and how of their PHI. If your HSP informs clients using clear posters, brochures, online Privacy statements via the HSP website and/or verbal scripts then your answer above should be Yes. If not, or if improvements are required, continue on to the next column.

Informing the Client – applies to the step 1.1 in the Sample Consent Management Process (See Section 4.1) as well as the samples included in sections 4.2, 4.3 and 4.4.



CONSENT TYPE: At a minimum, HSPs will have a clearly defined 'Consent type' for each process where PHI is collected, used or disclosed. A Consent type is either implied or express (refer to glossary) **Does your HSP have clearly defined Consent types - either implied or express for all collections, uses and disclosures of client PHI?** ☐ **Yes as is:** Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** **If you answered either "Yes – but needs improvement" or "No/Don't know":** If your HSP does not have a clearly defined Consent type for all collections, uses and disclosures of client PHI, or if you are not sure, then move on to the next column. **Consent Type –** refers to the steps 1.3 in the Sample Consent Management Process (Section 4.1)	Use the space below (or a separate sheet) to describe the Consent types your HSP uses today. For instance, do you use implied or express Consent for collection of PHI? Do you use implied or express Consent for use of PHI? Do you use implied or express Consent for disclosure of PHI? Note what forms, systems or materials are used in each process. Follow through with the instructions in each subsequent column until you have a plan of action for defining all your Consent types.	Determine whether implied or express Consent will be used for the collection, use and disclosure of PHI in your HSP going forward. Describe these in the column below. For any collection, use and disclosure of client PHI, implied or express Consent is acceptable so long as the client is informed (see the definitions in the glossary for the key benefits of one or the other). In addition to clearly defined Consent types for each collection, use and disclosure, it may be useful to look at the overall 'workflow' and determine whether any changes need to be made for efficiency or effectiveness. For example, it may be more effective to rely on implied Consent for collection and use, and express Consent for disclosure; or to rely on a single express Consent for all collection, use and disclosures.	Consider the difference between the existing process and the new design. What tasks, steps and forms may be required to establish the new process? Document these in the Action Plan column below. For example, if you are implementing express Consent for collecting assessment data you may decide to use a Consent form to support this (see Consent form template in section 4.5).

SCOPE OF CONSENT DIRECTIVE: At minimum, HSPs will provide clients the option to disclose (share) all their PHI or the option to share none. **Is your HSP able to at least give the client the option of disclosing (sharing) either all or none of their PHI?** ☐ **Yes as is:** Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** **If you answered either "Yes – but needs improvement" or "No/Don't know":** When it comes to the disclosure of PHI your HSP may provide clients with more of a choice than simply all or none. If so, your HSP is compliant with the CPF and you can mark the answer above Yes. If at a minimum clients are not provided with an all or none option, move on to the column to the right. **Scope of Consent Directive** – refers to the steps 1.3 in the Sample Consent Management Process (Section 4.1)	Use the space below (or a separate sheet) to describe how Consent to disclose or not disclose certain portions of client PHI is currently handled. When Consent is obtained (as discussed in the previous row in this worksheet), consider where and how the client's specific instructions with regards to who should see which parts of his/her PHI are applied. How are these instructions communicated with all staff to ensure that the client preferences are respected? How is it communicated with other HSPs? Follow through with the instructions in each subsequent column until you have a plan of action.	Determine the new scope of Consent Directive that your HSP will implement. Will you support "all or nothing" or go further? Will you support applying client Consent Directives to: all client PHI / groupings of PHI data / specific PHI data elements / specific staff or HSPs? Document your new scope of Consent Directives in the column below.	Consider the difference between the existing process and the new design. What tasks, steps and forms may be required to support the new scope of Consent Directives. Document these below. For example, does the new process require software to be implemented, forms to be updated, or other activities?

OBTAINING A CLIENT'S CONSENT AND CONSENT DIRECTIVES: HSPs that use express Consent and forms to obtain a client's Consent and Consent Directives should ensure that the forms used include: • a description of the PHI to be collected, used and disclosed • the purpose for which PHI was collected, used and disclosed • a clear statement of the client's Privacy Rights • the client's name, birthday, contact information, and substitute decision maker (if any). **If your HSP uses a form to obtain express Consent and/or Consent Directives does the form contain clear identification of the client; a description of the PHI, the purpose for its collection, use and disclosure, and a statement of client Privacy rights? Or, does your HSP use an implied Consent type, or a Consent type without forms?** ☐ **Yes as is - Also applies if express is NOT used, or if forms NOT used to obtain express Consent:** Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** This standard only applies to those HSPs that use the express Consent type and within that type use a form to	Use the space below (or a separate sheet) to list all your HSP's express Consent forms and describe their key components.	Consider which of the following pieces of information should be on a form used to obtain client Consent (or refer to the sample form provided (ref 4.5): • a description of the PHI to be collected, used and disclosed • the purpose for which the PHI was collected, used and disclosed • a clear statement of the client's Privacy rights • any conditions for Consent or Consent Directives • the client's personal information that clearly identifies the person, • substitute decision maker (if any) Also consider what changes may have to be made to processes to ensure the form is properly filled in. Document the new information items that your HSP will use on the new form in the column below.	Consider the difference between your existing forms and approaches to using them. Document these and a plan to address these differences in the Action Plan column below.

obtain client Consent. If neither is true in your HSP mark Yes above. If both are true and the forms used minimally have the components listed you can also mark Yes above. Otherwise continue to the next column to the right. **Obtaining a Client's Consent and Consent Directives –** refers to the steps 1.4 in the Sample Consent Management Process (Section 4.1) and the sample Consent form in section 4.5.			

CONSENT DIRECTIVE OVERRIDE / DISCLOSURE WITHOUT CONSENT: HSPs will clearly define a process to support the instances in which it may be necessary to override a client's Consent Directive by obtaining a new, express Consent from the client; or disclose a client's PHI without Consent as per PHIPA Section 40(1) "where the custodian believes on reasonable grounds that the disclosure is necessary for the purpose of eliminating or reducing a significant risk of bodily harm to a person or group of persons". **Does your HSP have clear process to manage both client and staff override of the Consent Directives?** ☐ **Yes as is:** Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** **If you answered either "Yes – but needs improvement" or "No/Don't know":** Once a client establishes a Consent Directive it should be followed by an HSP. There are two exceptions: If the HSP finds a need to override the client's Consent Directive they must ask the client for express Consent prior to overriding their initial Consent Directive. This express Consent should be documented. If the HSP staff needs to disclose the client's PHI without Consent they should do so within legislative guidelines and documented HSP policy and practice. If your HSP has clearly defined procedures to support these cases then answer Yes above. Otherwise continue to the column to the right. **Consent Directive Override/Disclosure Without Consent** – refers to the steps 1.4 in the Sample Consent Management Process (Section 4.1) and the sample consent form in section 4.5.	Use the space below (or a separate sheet) to describe your HSP's current approach to client override and disclosure without Consent and follow through with each subsequent column to build a new approach and plan of action.	For client override of their own Consent, determine how your HSP will collect the express Consent from the client. What new forms and documentation will be used?For disclosing a client's PHI with Consent as per PHIPA Section 40(1), how will your HSP document the staff justification of reasonable grounds? What forms, templates or other tools are required?Document the new Override/Disclosure Without Consent process and tools in the column below.	Consider the difference between the existing approach to Consent Directive override and the new design. What new tasks, steps and forms may be required? Document these in the Action Plan column below. Note: Currently the consent directive override (privacy override) function is disabled in IAR. Therefore all over consent override decisions should be well documented locally. The decision should be uploaded into IAR as a normal consent directive.

RECORDING THE CONSENT DIRECTIVE: HSPs should properly store and archive any Consent forms and document in a log any client Consent Directives. **If your HSP uses express Consent and forms to obtain it are these properly stored and archived? In addition, regardless of whether your HSP uses express or implied Consent, does your HSP log all client Consent Directives?** ☐ **Yes as is - Applies if the answer to both questions above is yes.** Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** **If you answered either "Yes – but needs improvement" or "No/Don't know":** If your HSP uses forms to obtain express Consent from clients check that these (or copies of these) are stored safely, securely and in ways that allow for quick staff retrieval and review. Check as well that your HSP keeps a separate log record of each client's Consent Directive such that staff can quickly and securely check for this information. If your HSP manages Consent forms and directives accordingly then mark Yes above. Otherwise, continue to the next column on the right. **Recording the Consent Directives** – refers to the steps 1.7, 2.5 in the Sample Consent Management Process (Section 4.1)	Use the space below (or a separate sheet) to describe the process and systems used to store Consent forms and any process or systems that help staff determine if a client has a Consent Directive.	Design and document a new approach to storing, archiving and retrieving any client Consent forms. Similarly, design and document a means of logging and checking on the presence of client Consent Directives. Consider customizing and using the Sample Directive Log [ref 4.6] In either case, consider the use of technology to support security and facilitate rapid information search and retrieval.	Consider the difference between your existing forms and approaches to using them. Document these and a plan to address the differences in the Action Plan column below.

REGISTERING AND UPDATING CONSENT DIRECTIVES: HSPs should have consistent processes and/or systems that ensure Consent Directive is properly registered/updated on a client's paper chart or in an electronic system that hosts the client's PHI. **Does your HSP have a process in place that ensures Consent Directives are properly registered/updated on a client's paper chart or in an electronic system that hosts the client's PHI?** ☐ **Yes as is**: Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** **If you answered either "Yes – but needs improvement" or "No/Don't know":** Once your HSP has obtained a Consent Directive from a client it is important to ensure that Consent Directive is properly registered/updated on a client's paper chart or in an electronic system that hosts the client's PHI. This should be done as soon as is practical. In addition, if the client changes or updates his or her Directive, the previously registered Consent Directive has to be updated properly. If your HSP is registering client Consent Directives then mark Yes above. Otherwise continue to the next column on the right. **Registering and Updating Consent Directives** – refers to the steps 1.5, 1.9, 1.10, 2.3, 2.7, 2.8 in the Sample Consent Management Process (Section 4.1) and to the consent log template in section 4.6.	Use the space below (or a separate sheet) to describe any process or system that supports Staff knowing or finding out about client Consent Directives. Consider what information is recorded on a client's chart or within your HSP's health information system.	Design and document a new approach to ensuring Consent Directive is properly registered/updated on a client's paper chart or in an electronic system that hosts the Client's PHI. In either case, consider the use of technology to register and update the Consent Directive.	Consider the difference between your existing forms and approaches to using them. Document these and a plan to address the differences in the Action Plan column below.

ENFORCING CONSENT DIRECTIVES: HSPs should have administrative and technical controls in place to ensure that client Consent Directives are being enforced. **Does your HSP use consistent administrative or technical controls to enforce client's Consent Directives – for instance by restricting access to all client PHI if the client has withdrawn consent (by moving PHI to a different filing cabinet or by blocking it electronically)** ☐ **Yes as is:** Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** **If you answered either "Yes – but needs improvement" or "No/Don't know":** Once your HSP has obtained a Consent Directive from a client it is important to ensure it is reliably followed. This may involve having administrative controls such as limits and logs to access locked paper files or, in the case of electronically stored client PHI, using technological restrictions and logging to manage and record staff access. If your HSP is using these or similar approaches to manage access, use and sharing of PHI then mark Yes above. Otherwise, continue on to the column to the right.	Use the space below (or a separate sheet) to describe the processes and systems used to limit and record access to client PHI in your HSP.	Design the systems and processes appropriate to your HSP's PHI management that will support enforcement of client Consent Directives. Consider the use of technology to support the enforcement of the client's Consent Directives.	Consider the difference between your existing forms and approaches to using them. Document these and a plan to address the differences in the Action Plan column below.

IMPLEMENTING CONSENT MANAGEMENT PROCESS (AND CHANGES): HSPs should provide communications and training to ensure staff and volunteers are consistently capable of supporting the Consent management process. **Are all staff and volunteers fully aware of and capable of supporting the HSP Privacy policies, tools and procedures?** ☐ **Yes as is:** Further work on this specification not needed ☐ **Yes - but needs improvement** ☐ **No/Don't know** **If you answered either "Yes – but needs improvement" or "No/Don't know":** Especially if your HSP is planning changes to its Privacy processes, forms and/or policies as part of implementing the Consent management process, it is important that staff are aware of, capable of and prepared to support these properly and consistently. Communications and training are key elements of change management. If your HSP's process already fully meets the Consent requirements, providing yearly 'refresher' training for staff in Privacy, as well as similar education for new hires, will ensure consistent performance. If you are satisfied with staff' support of HSP Privacy practice then mark Yes above. Otherwise continue to the column to the right.. Refer to the sample Consent Management Process Implementation plan and Implementation checklist in sections 4.7 and 4.8.	Use the space below (or a separate sheet) to identify the key process changes or Privacy components that require additional staff support. Look through all the Consent management process changes and list components with action plans that may benefit from communications and training.	For each change or area of concern in Privacy, consider what communications or training will best support staff and volunteers in their Privacy related roles.	Consider how best to fulfill the communications and training requirements you have outlined.

4. Samples and Templates

This section contains samples and templates provided for your convenience. You may choose to use them as the starting point to design or refine your HSP's Consent management process as you see fit. You may also continue to use your existing processes, posters, brochures and other materials if they already meet the design you have developed in Section 3.

Please note that your HSP's alignment with the CPF may require more than simply adopting the following samples. It is important that you review your processes as described in Section 3.

Once again, note that the CPF was designed specifically to support the implementation of assessments across community care sectors. That said, the following samples and templates are designed in accordance with PHIPA and represent good Privacy practice. HSPs may modify and use them across their business as they see fit.

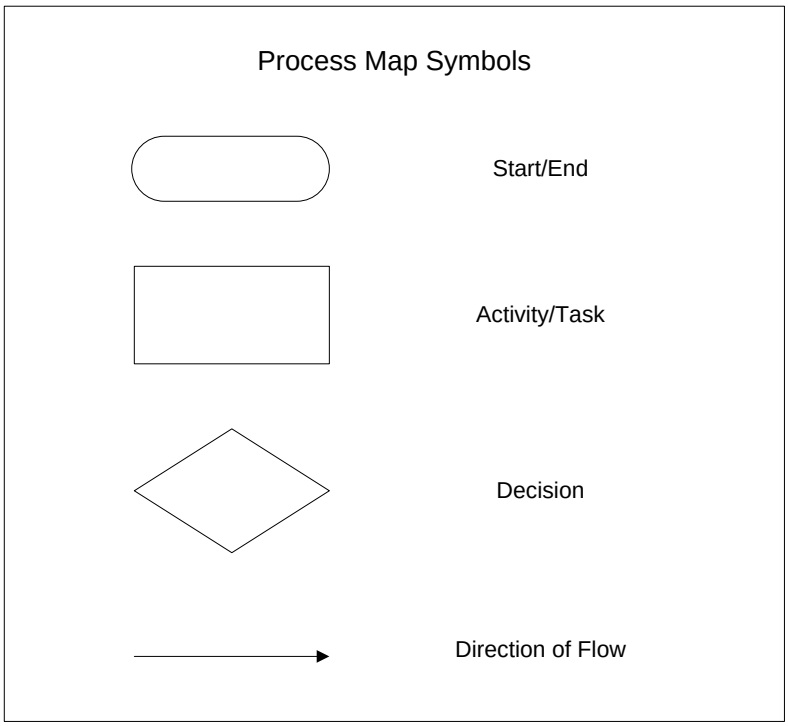
4.1 Sample Consent Management Processes

The following two sample Consent management processes describe step-by-step the key elements of a sustainable Consent management process. One describes the process a 'generic' Health Service HSP might follow to obtain Consent or Consent Directives; and the other describes the process for updating Consent Directives.

Each process is presented both as a map and as a written outline (table) of the steps involved. You can use these as the basis for designing similar processes in your own HSP or simply as a reference. Reference numbers link the tasks in these samples to the analysis questions in the Analysis and Design Worksheet in section 3 (see the dashed box at the bottom of the first column of each page of the worksheet).

The term "process map" refers to a diagram that describes a workflow or set of connected activities. It shows who is responsible (the role names in each horizontal row), what needs to be done (the boxes), and when each activity happens (the order of the boxes). The table also suggests supporting materials for tasks as appropriate.

The elements in a process map each have different meaning as outlined in the legend below.



How to Use These Sample Processes

Click here to access a version of the sample processes that you can modify.

You can use these samples as a starting point to describe your own HSP's Consent management process: either the current process or one you are designing for a future implementation. Start by choosing the appropriate map or, if you are more comfortable, writing out a process rather than drawing it, start with the appropriate process table:

- If you are mapping or outlining the decisions you made in the Analysis and Design Worksheet (Section 3) remember that the reference box at the bottom of the first column of the Worksheet links it to the activity/step number in each sample process
- Add, remove and/or update the tasks/steps and supporting materials (in the process map or associated process table on the next few pages) based on your HSP's Consent model
- Change the tasks/steps and responsible people on the map or table as appropriate. If using the table, write out each activity under the heading "Tasks/Steps" and list any associated materials in the same row under the heading "Supporting Materials". Identify the role involved under "Responsible Person".

1. Sample Consent Management Process: Obtain Consent/Consent Directive (Implied or Express)

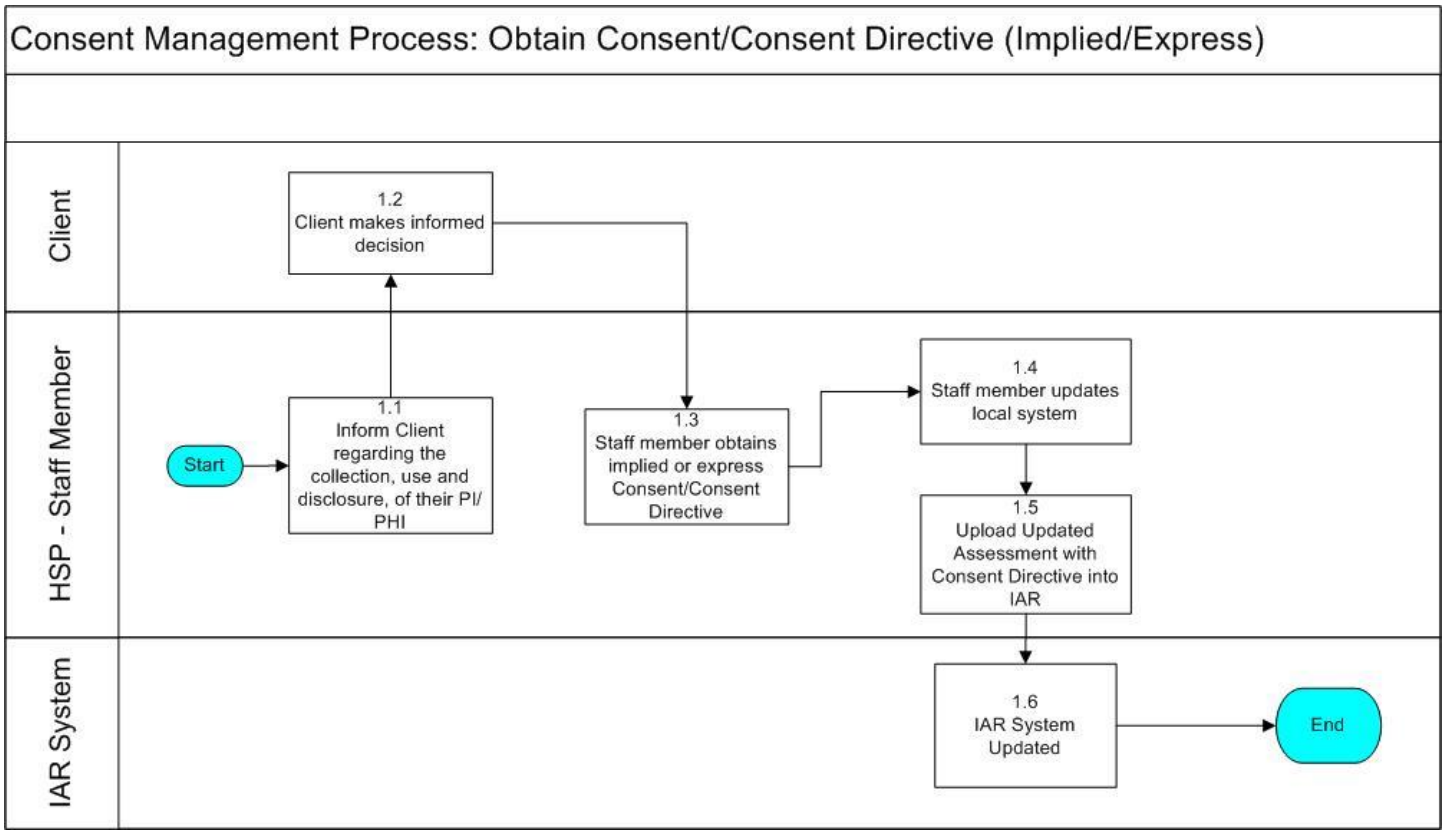


Table 1: Obtain Consent/Consent Directive Process (Implied or Express)

No.	Task / Step	Responsible Person	Supporting Material
1.1	Prior to conducting the assessment, the staff informs client regarding the collection, use and disclosure of their PI/PHI and the client's privacy rights.	Staff members	Brochure (section 4.2), Poster (section 4.3), Consent Communication script (section 4.4)
1.2	Client makes an informed decision (either to consent or to withhold their consent) initiating a consent directive	Client	
1.3	HSP Staff Member obtains implied or express consent (or consent directive) according to existing HSP consent process	Staff members	Consent form template (section 4.5)
1.4	Staff members update local system with the consent directive received according to existing consent process (this should be done as soon as is practical).	Staff members	
1.5	The assessment with consent directive is uploaded to IAR System	Staff members	
1.6	The IAR System is updated with the current consent directive	Privacy Officer / delegate	Consent Directive registry template (section 4.6)

2. Sample Consent Management Process: Update Consent Directive (Withdraw/Reinstate)

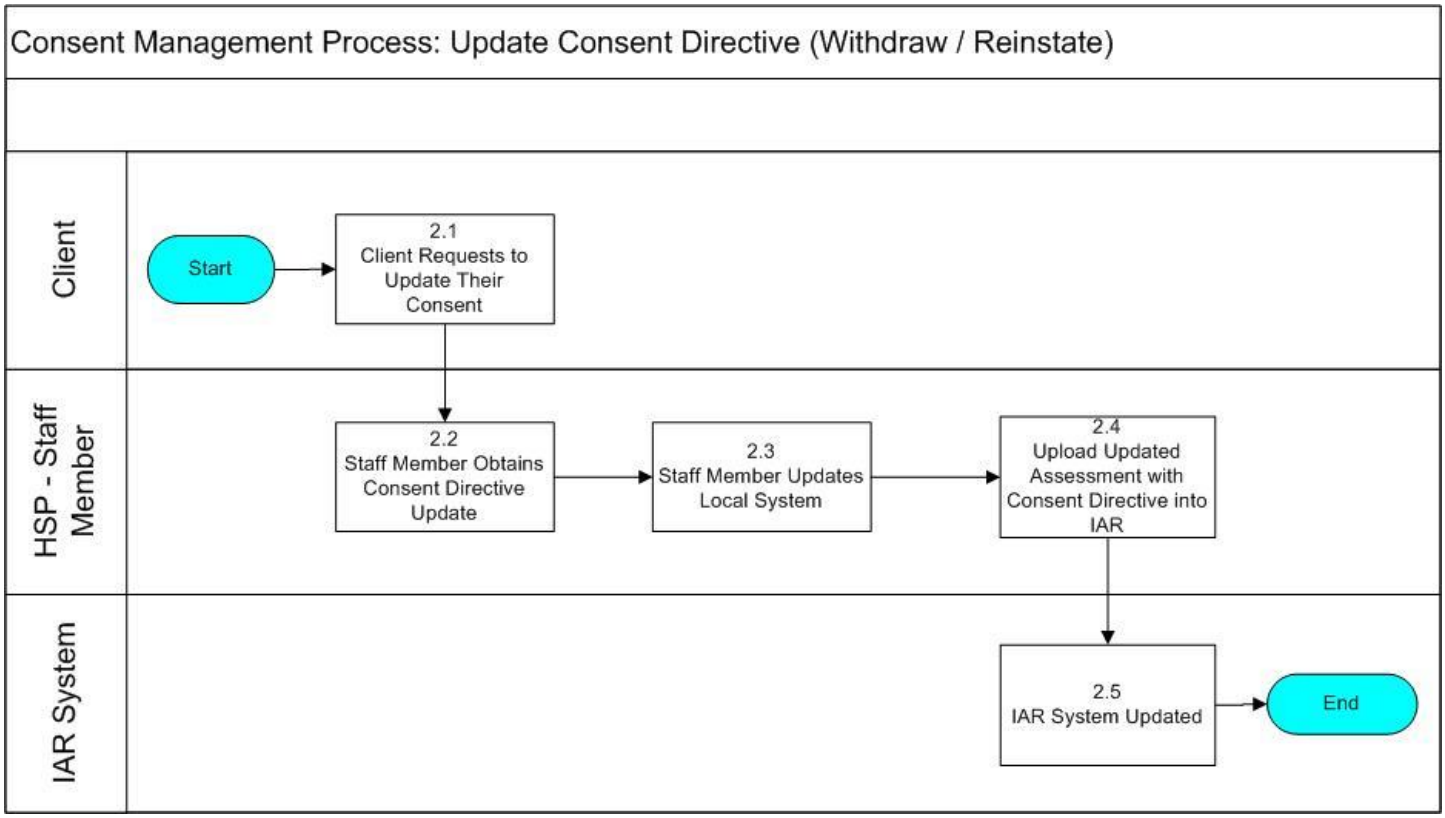


Table 2: Update Consent Directive (Implied or Express)

No.	Task / Step	Responsible Person	Supporting Material
2.1	Client requests to update their consent directive (withdraw or reinstate)	Client	
2.2	Staff obtains verbal or written consent or consent directive according to existing HSP consent process.	Staff Members	Consent Form template
2.3	Staff members update local system with the consent directive received according to existing consent process (this should be done as soon as is practical).	Staff Members	
2..4	The assessment with updated consent directive is uploaded to IAR System		
2.5	The IAR System is updated with the current consent directive		

4.2 Sample Informed Consent Brochure

Purpose

The informed Consent brochure is one way to inform clients of Privacy and Consent issues for the purpose of informed Consent. This sample brochure covers all key information for informed Consent in a brochure format.

How to Use This Sample Consent Brochure

This brochure can be customized to meet your HSP's particular requirements and used in line with the decisions you've made to develop or refine your HSP's Consent management process.

Click here to access a version of this consent brochure to customize.

Note: The image shown below is a low-resoution example of the actual brochure template. The brochure template is available as an electronic file from (>insert web site<)

(This page is intentionally left blank.

Your Privacy Choices

Please speak to your usual health service provider or our Privacy Officer, if you want to:

See your own information: You can request a copy of your assessments and/or Coordinated Care Plan.

Correct your own Assessments or Coordinated Care Plan: You can ask us to correct any errors or omissions in your assessments or Coordinated Care Plan.

Opt-Out: You may choose not to share your information with other health service providers. You may also choose not to share anything about you including name, phone number, address, etc.

<<Insert potential positive and negative consequences for sharing or not sharing the assessment>>

To choose to withhold your consent to share your assessment, Coordinated Care Plan or your basic identifying information, call the Consent Call Centre toll free at: **1-855-585-5279 (TTY 1-855-973-4445).**

If you would like to know more about how your Personal Health Information is handled and shared with our partner organizations, or have concern about our privacy practices, feel free to ask our Privacy Officer. They will be happy to answer any questions that you might have.

<<Insert Privacy Officer contact information>>

The Privacy Commissioner

If you have any issues or concerns about how your health information is being handled, you have the right to contact the **Information and Privacy Commissioner of Ontario** at:

2 Bloor Street East, Suite 1400
Toronto, ON M4W 1A8
Telephone: 416-326-3333
or, 1-800-387-0073
Online: http://www.ipc.on.ca

Privacy and Your Assessment

A Guide to the Collection, Use and Disclosure of Your Personal Health Information

<HSP logo here>

Your Personal Health Information

We use your personal health information (PHI) to provide you with health services. That information is used and sometimes shared with your other providers to determine your health service and support needs and may also be used to coordinate care planning.

Your assessments and Coordinated Care Plan may include information on:

- Your physical and mental health
- Your personal and health history
- <<insert other information that your HSP may collect or use >>

Unless you tell us not to, your personal health information will be shared with other organizations that are providing you with health services, both now and in the future. Sharing assessments, including Coordinated Care Plans, gives health service providers in your community the most complete and up-to-date information about you. Holistic health care depends on a holistic view of your health data to identify and serve your needs.

Sharing your information

We use a secure electronic system to share your health information with other health service providers. This allows them to view the information they need to provide you with the services you need.

If you have agreed to share your Personal Health Information, the information in your assessment and Coordinated Care Plan will be used to:

- Provide health support and services based on your needs
- Make sure your health service providers have the most up-to-date and complete record of your health history and needs
- Help us understand your care goals and to provide the services you need
- Make sure everyone is getting the right support and services

Protecting Your Information

The information in your assessments and Coordinated Care Plan is your information. Our priority is protecting your privacy while delivering high quality care. In the assessment and coordinated care processes, we only collect the information we need to determine your service and support needs. This information cannot be used for any other purposes without your permission unless required by law[1].

- Your health information is kept in a secure place
- Your health information will only be viewed by people we have authorized.
- All health information custodians have confidential legal obligation to protect your privacy.
- When a person views your information, it is recorded in a log. We will review this log regularly to make sure there has been no unauthorized access to your information.
- We will investigate any suspected breach or unauthorized access to, or use of, your Personal Health Information
- Your health information may be used for secondary purposes as authorized by law (e.g. statistical reports for Ministry of Health)

[1] For example, the College of Physicians and Surgeons may need access to information to validate the quality of care you receive from a physician.

4.3 Sample Consent Poster

Purpose

The informed Consent poster is one way to inform clients of Privacy and Consent issues for the purpose of informed Consent. This sample poster covers all key information for informed Consent in a poster format.

How to Use This Sample Consent Poster

This poster can be customized to meet your HSP's particular requirements and used in line with the decisions you've made to develop or refine your HSP's Consent management process.

Click here to access a version of the sample poster that you can customize.

If your health service provider (HSP) uses other means to inform the client of Privacy and Consent issues, this poster can be simplified to convey only the key Privacy message points. However, if this poster is your HSP's primary means of informing the Client, the content must include all key elements of informed Consent (shown in the sample poster on the next page).

Note: The image shown below is a low-resoution example of the actual poster template. The poster template is available as an electronic file from (>insert web site<)

Privacy and Your Assessment

<<HIC Logo>>

Know Your Rights

Sharing your information is important...

Unless you tell us not to, your personal health information will be shared with other organizations that are providing you with health services, both now and in the future. Sharing assessments, including Coordinated Care Plans, gives health service providers in your community the most complete and up-to-date information about you. Holistic health care depends on a holistic view of your health data to identify and serve your needs.

Your assessments and Coordinated Care Plan may contain information on:

- Your physical and mental health
- Your personal and health history
- <<Insert other information that your HSP may collect or use>>

We are accountable for protecting your information.

The information that is in your assessments and Coordinated Care Plan are used only by Health Service Provider who are authorized to provide you with health support and services. These people and the systems are required to keep your information confidential.

When it comes to your health information, you can choose to:

- **Request to see your own assessment or Coordinated Care Plan; and**
- **Ask us to correct any errors or omissions; and**
- **Tell us if you do not want to share your information**

To learn how to your information is being used and shared or have any concerns about our privacy practices, you may contact our Privacy Office at <<insert contact info here>>

Withholding consent for sharing your assessments or Coordinated Care Plan in the electronic system means that they will not be viewable by individuals providing your care at other providers. You can reach the Consent Call Centre to instruct them to not to share your information by calling toll free to 1-855-585-5279 (TTY 1-855-973-4445). Note that your information may still be made available to organizations with the legal authority to view health information without consent, and for secondary uses (e.g. statistical reports for Ministry of health)

If you have concerns about how your health information is being handled, you have the right to contact the Information and Privacy Commissioner of Ontario at: 2 Bloor Street East, Suite 1400 Toronto, ON M4W 1A8 Telephone: 416-326-3333 or, 1-800-387-0073

4.4 Sample Consent Communication Script

Purpose

This sample provides a standardized script that can be used by staff members to communicate about privacy and consent with clients. The template covers all key information for informed Consent, including information to be collected, used and shared; the purposes; the positive or negative consequences for sharing or not sharing; and the client's Privacy rights.

How to Use This Sample

This script can be customized to meet your health service provider's particular requirements and used in line with the decisions you've made to develop or refine your HSP's Consent management process.

Click here to access a version of the sample script that you can modify.

To customize the script:

- Add information specific to your HSP in the areas marked with "**<< >>**".
- Amend the content according to your HSP's Consent type and process.

General Privacy and Consent Communication Script

If your system does not have a way of recoding client/patient consent, you may print this document out and complete it as a form to record consent.

Do not use this with clients/patients until you have reviewed and updated it to match your particular circumstances. The use of << brackets >> indicates text that you must adapt to your HSP.

At a minimum, point #1 and #2 should be covered with the clients/patients either with this script or by a poster/brochure.

The Collection, Use and Disclosure (Sharing) of <<Client/Patient's Assessments and/or Coordinated Care Plans>>: What we collect and why we need it

We would like to complete an **<<Assessment Type or Coordinated Care Plan>>** for you. The **<<Assessment Type or Coordinated Care Plan>>** will include information about you, such as your medical conditions, your goals and other information about you that will help your care team to coordinate and provide care to you.
We collect, use and disclose your personal health information in order to provide you with services, to coordinate your care planning with others and to support those that do provide you with services. We will also use your information for a variety of secondary

purposes such as quality control, generating reports required by the Ministry of Health or other purposes that are allowed by law.

The client has heard and understood what we collect and why we need it: ☐

1. Sharing of Client/Patient's Coordinated Care Plans – what client/patient's consent means

If you give us your consent to share your information, only those health care workers who have been authorized by their organization for this purpose will see your **<<Assessment Type or Coordinated Care Plan>>.** Your **<<Assessment Type or Coordinated Care Plan>>** information will be stored in a security electronic system and will be used by health care workers providing you with service so you don't have to repeat yourself and so that they will have important information about you. Do you give us your consent to share your information?

Optional: If you give us your consent, this may mean:

- **<<Positive and negative consequences for sharing the Assessment Type or Coordinated Care Plan>>**

If you choose to withhold your consent and not share your Assessment Type or Coordinated Care Plan, this may mean:

- **<<Positive and negative consequences for not sharing the Assessment Type or Coordinated Care Plan>>**

The client has heard and understood what their consent means: ☐

2. Future Consent

Would you like to maintain this consent for the future? If you do, this means that each time your **<<Assessment Type or Coordinated Care Plan>>** is updated, the consent that you provide today will automatically be applied to those updates and we will not ask you these consent questions each time your Coordinated Care Plan is updated, otherwise, we will ask you for your consent each time the **<<Assessment Type or Coordinated Care Plan>>** is updated.

The client has agreed to future consent for this assessment: ☐

(If the client/patient gives consent, skip to #5. If the client/patient wants to withdraw consent, please go to point #4a)

3. Consent Withdrawal Options

a) **HSP specific withdrawal of consent --** If you do not want to share this **<<Assessment Types or Coordinated Care Plans>>** information with other health care workers, you can let me know today or inform our staff anytime in the future, and we will make sure the **<<Assessment Types or Coordinated Care Plans>>** will not be shared. Do you consent to sharing this **<<Assessment Types or Coordinated Care Plans>>** ?

Consent Granted: ☐ **Consent Denied:** ☐

Do you have concerns about sharing other **<<Assessment Types or Coordinated Care Plans>>** that have been completed before now? If client/patient is concerned about all of their Coordinated Care Plans in the secure electronic system go on to point #4b. If not, go to #5.

b) **IAR Consent Directive** – Would you want all of your **<<Assessment Types or Coordinated Care Plans>>** *blocked* -- Or do you want none of your **<<Assessment Types or Coordinated Care Plans>** information shared, even the **<<Assessment Types or Coordinated Care Plans>** information gathered at other Health Service Providers? You can call the Consent Call Centre at 1-855-585-5279 during regular business office hours. This will ensure that no one will be able to access any of your **<<Assessment Types or Coordinated Care Plans>**. Only your basic identifying information, like name, phone number and city will be there. This basic identifying information is used in the event that you change your mind and decide to share your **<<Assessment Types or Coordinated Care Plans>** in the future. Your health service provider will be able to find you as well as your shared Coordinated Care Plans. Is this okay with you?

The client/patient wishes to apply an IAR level consent directive: ☐ **(Leave blank for no)**

If client/patient is concerned about having basic identifying information (i.e. name, phone number, city, date of birth, gender, etc.) in the IAR, go on to #4c. Otherwise go to #5.

c) **IAR Consent Directive with basic identifying information blocked –** If you do not want to share your basic identifying information, like name, phone number and city, you can have that blocked by calling the Consent Call Centre at 1-855-585-5279 during regular business office hours. By telling them that you do not want to share your personal information; your identifying information will not be visible.

The client/patient also wishes to suppress personal information: ☐ (Leave blank for no)

For any IAR Level Consent Directive add: We call this instruction a Consent Directive. It will take effect in **<<# number of business days>>** after you inform the Consent Call Centre that you want your assessment/personal information blocked.

The client/patient needs assistance calling the Consent Call Centre: ☐ (Leave blank for no)

4. Your Privacy Rights

You can request a copy of your **<<Assessment Type or Coordinated Care Plan>>** information in your file by contacting us. You also have the right to request a correction or amendment to your **<<Assessment Type or Coordinated Care Plan>>** information, or log a complaint if you feel that we have not addressed your privacy concerns properly. You should know that you will need to identify yourself to the Privacy Officer (or designated staff) in order to make privacy related requests. You may need to provide the following information **<<Identification Information>>.**

5. Need More Information or Have Questions?

If you would like to know more about how your Personal Health Information is handled and shared with other Health Service Providers or have concerns about your privacy, you can contact the Privacy Officer at **<<HSP name>>.** They will help you understand what it means to share your assessments and/or Coordinated Care Plan and will be able to answer your questions. Please contact our designated Privacy contact at **<<Privacy Contact Information>>**

Name and/or ID of the client patient:	
Name of the person obtaining the consent:	
Date that the consent was obtained:	

4.5 Sample Consent Form

Purpose

This Consent form template provides a standardized form to collect a client's instruction with regards to the collection, use and disclosure of client assessments. The template includes all key elements of the Consent Directive, including:

- A high level introduction of collection, use and disclosure of assessments
- A description of the client's privacy rights
- The client's Consent Directive
- The minimum personal information required to acurately identify the client
- A space to document the client's substitute decision maker if applicable
- Space for the client or SDM's signature

How to Use This Sample

This form can be customized and used as your HSP's Consent form if your HSP has chosen an express Consent type.

Click here to access a version of the sample form that you can customize.

HSPs, that practice implied consent or verbal express consent, do not need to use the consent form when collecting the assessment from the client. However, if an explicit Consent Directive is articulated by the client, the HSP must capture and document the Consent Directive either using a Consent form, or logging/registering the verbal Consent Directive.

This form can be customized to meet your HSP's particular requirements and used in line with the decisions you've made to develop or refine your HSP's Consent management process.

To customize the form:

- Add information specific to your HSP in the areas marked with "**<< >>**".
- Amend the content according to your HSP's specific Consent type and process

<<HSP Name>>

Consent Directive to Sharing Assessment Data

We are constantly working to provide you with health care services that meet your needs and enable you to seek those services at organizations across the province. In doing so, we may need to share your assessment data via fax or an electronic sharing system with other health service providers, who need to review the assessment data in order to provide services to you.

You have the right to withhold or withdraw your consent to share your personal health information at any time.

We may need to share the assessment with other health service providers, who will need to review it in order to provide services to you. Do you consent to the sharing of your assessment?

☐ Yes, I consent	☐ No, I don't consent	To the sharing of the <<assessment ID>> collected by <<HSP Name>> <<on DATE >>. I understand my choice will only be applied to the sharing of this assessment with other health service providers via fax or an electronic sharing system, and will be effective within <<#>> Business Days. Note: This consent does *not* apply to the copies of my assessments that other HSPs have already received.
☐ Yes, I consent	☐ No, I don't consent	To the sharing of all my previous and future assessments, collected by <<HSP Name>>. I understand my choice will only be applied to the sharing of assessments collected by <<HSP Name>> with other health service providers and will be effective within <<#>> Business Days. Note: This consent does not apply to the copies of my assessments that other HSPs have already received.

Name: _____

Signature: _____

Date: (MM/DD/YYYY)

Substitute Decision-Maker (if applicable):

_____

Name: _____

Date of Birth : (MM/DD/YYYY)

Signature:_____

Date: (MM/DD/YYYY)

Relationship _____

Client/Patient Information (information are collected for patient identification) The fields below are used for the purposes of identifying the individual who is consenting so that their Consent can be properly managed.

Name:

Date of Birth: (MM/DD/YYYY)

Telephone No:

Address:

An electronic sharing system is used to share your assessment data with other health service providers, who need to review the assessment data in order to provide services to you. If you wish to consent or withhold your consent to the sharing of all your assessments in the electronic sharing system, please contact the support centre by calling Telephone: (###) ###-####.

Please refer to the <<brochure/poster >> for additional information regarding the collection, use and disclosure of your personal health information. <<Contact Information / Website>>

4.6 Consent Log Template

Purpose

This Consent log can be used to log Consent/Consent Directives as requested by clients.

How to Use This Template

This log can be customized to meet your HSP's particular requirements and used in line with the decisions you've made to develop or refine your HSP's Consent management process.

Click here to access a version of the log that you can modify.

The first row of data is provided only as an example of how client information can be recorded in the table.

Ref. No.	Organization Name	Client/Patient Name and #	Consent Directive Requested	Received By	Received Date	Registered by	Registration Date
H201001	*HSP 1*	*John Smith 54321*	*Lock all assessment data*	*David Jones*	*13/01/2016*	*Jane Doe*	*15/01/2016*

4.7 Sample Development Checklist

Purpose

This Consent management development checklist is provided as an example to assist you with tracking and reporting on the implementation progress of the Consent management changes that you have identified using this guide.

How to Use This Sample

This checklist can be customized to list your HSP's development activities and used in line with the decisions you've made to develop or refine your HSP's Consent management process.

Click here to access a version of the sample development checklist that you can modify.

Amend the content according to your HSP's specific requirements.

1.	**INFORMING THE CLIENT**: In order to align with the Common Privacy Framework, all clients in our HSP will be clearly and fully informed prior to their giving Consent for PHI collection, use and disclosure.		☐ Already Fully Aligned	
a.	*Replace this text – use rows to describe key change tasks required to achieve alignment with the CPF*	By Whom:	By When:	☐ Done
b.	*Add more rows as required*	By Whom:	By When:	☐ Done
c.		By Whom:	By When:	☐ Done
2.	**CONSENT TYPE**: In order to align with the Common Privacy Framework, our HSP will have clearly defined Consent types - either implied or express - for all collection, use and disclosure of client PHI.		☐ Already Fully Aligned	
a.	*Replace this text – use rows to describe key change tasks required to achieve alignment with the CPF*	By Whom:	By When:	☐ Done
b.	*Add more rows as required*	By Whom:	By When:	☐ Done
c.		By Whom:	By When:	☐ Done
3.	**SCOPE OF CONSENT DIRECTIVE**: In order to align with the Common Privacy Framework, our HSP will at least be able to give clients the option of disclosing/sharing ALL their PHI or disclosing/sharing NONE of their PHI.		☐ Already Fully Aligned	
a.	*Replace this text – use rows to describe key change tasks required to achieve alignment with the CPF*	By Whom:	By When:	☐ Done
b.	*Add more rows as required*	By Whom:	By When:	☐ Done
c.		By Whom:	By When:	☐ Done
4.	**CONSENT DIRECTIVE OVERRIDE / DISCLOSURE WITHOUT CONSENT:** In order to align with the Common Privacy Framework, our HSP will have a clear process to manage both client and staff override of Consent Directives. (note: IAR currently does not support privacy override) override records are managed locally)		☐ Already Fully Aligned	
a.	*Replace this text – use rows to describe key change tasks required to achieve alignment with the CPF*	By Whom:	By When:	☐ Done
b.	*Add more rows as required*	By Whom:	By When:	☐ Done
c.		By Whom:	By When:	☐ Done
5.	**OBTAINING A CLIENT'S CONSENT DIRECTIVES**: In order to align with the Common Privacy Framework, all Consent and Consent Directive forms will contain clear identification of the client; a description of the PHI; the purpose for its collection, use and disclosure; and a statement of client Privacy rights.		☐ Already Fully Aligned	
a.	*Replace this text – use rows to describe key change tasks required to achieve alignment with the CPF*	By Whom:	By When:	☐ Done
b.	*Add more rows as required*	By Whom:	By When:	☐ Done
c.		By Whom:	By When:	☐ Done

6.	**RECORDING THE CONSENT DIRECTIVE** In order to align with the Common Privacy Framework, all Consent forms will be properly stored and archived and all client Consent Directives will be logged.		☐ Already Fully Aligned	
a.	*Replace this text with the tasks - if any - required to achieve alignment*	By Whom:	By When:	☐ Done
b.	*Add more rows as required*	By Whom:	By When:	☐ Done
c.		By Whom:	By When:	☐ Done
7.	**REGISTERING AND UPDATING CONSENT DIRECTIVES**: In order to align with the Common Privacy Framework, we will have a process in place that ensures client Consent Directives are properly registered and updated on a client's paper chart or in the electronic system that hosts client PHI.		☐ Already Fully Aligned	
a.	*Replace this text with the tasks - if any - required to achieve alignment*	By Whom:	By When:	☐ Done
b.	*Add more rows as required*	By Whom:	By When:	☐ Done
c.		By Whom:	By When:	☐ Done
8.	**ENFORCING CONSENT DIRECTIVES**: In order to align with the Common Privacy Framework, we will use consistent administrative and technical controls to enforce client Consent Directives.		☐ Already Fully Aligned	
a.	*Replace this text with the tasks - if any - required to achieve alignment*	By Whom:	By When:	☐ Done
b.	*Add more rows as required*	By Whom:	By When:	☐ Done
c.		By Whom:	By When:	☐ Done

4.8 Sample Consent Management Process Implementation Plan

STEP 4

IMPLEME

Purpose

This Consent management process implementation plan sample is provided to assist you in the creation of a rollout plan to for the consent management process that you have analyzed, designed and developed using this guide.

How to Use This Sample

This plan can be customized to meet your HSP's particular requirements and used in line with the decisions you've made to develop or refine your HSP's Consent management process.

Click here to access a version of the sample implementation plan that you can modify.

Amend the content according to your HSP's specific requirements.

Sample Consent Management Process Implementation Plan

Purpose:

The purpose of this implementation plan is to define the activities, resources and timeline to implement the Consent management process.

Objective:

The objective of the Consent management process implementation is to:

- Establish a consistent Consent management practice to manage the client's Consent/Consent Directive
- Ensure compliance with PHIPA Consent requirements

- Promote the awareness of the Consent management practices to all staff and whoever participate in the provision of healthcare services
- Ensure the frontline staff address any Consent related issues appropriately in accordance with the defined process

Implementation Tasks:

No.	Tasks	Responsible Person	Timeline
1 - Awareness	*Senior management announces the Consent management process to all staff* • *What is changing* • *Why it is changing* • *Impact to staff* • *Impact to Client* • *Implication of not changing*	*Communications/Senior Management*	*Jan 1 – Jan 10*
2 - Knowledge	*Provide information on:* • *Privacy* • *Consent* • *PHIPA* *Communicate the Consent management process with all staff and whoever involved in the provision of healthcare services*	*Privacy Officer/ Communications*	*Jan 11 – Jan 20*
3 - Ability	*Training* • *Training to staff who collect Consent (assessors)* • *Training to management* • *Training to others as required* *Need to include:*	*Privacy Officer/ Communications*	*Jan 21 – Jan 31*

	• *Consent* • *Business Process* *Provide awareness training to all staff and whoever is involved in the provision of healthcare services*		
4 - Reinforcement	*Provide Consent management process training to the frontline staff* • *Strategies for ongoing reinforcement of information* • *Opportunities for review, reflection, questions* • *Ongoing communication*	*Lead of Clinician/ Communications*	*Feb 1 – Feb 10*

5. Appendix A: Legislative Requirements

Personal Health Information Protection Act (PHIPA[4]) establishes the rules for the collection, use and disclosure of personal health information (PHI) and provides individuals with the right to:

- access and to require the correction or amendment of, personal health information;
- obtain an independent review and resolution of complaints with respect to personal health information; and
- secure remedy for contraventions of the Act.

PHIPA specifically sets out the requirements with regards to the Consent for the collection, use and disclosure of personal health information.

PIII of PHIPA defines the requirements for Consent concerning personal health information. The Consent of an individual for the collection, use and disclosure of personal health information by a health information custodian (section 18(1) of PHIPA):

(a) must be a Consent of the individual;

(b) must be knowledgeable;

(c) must relate to the information; and

(d) must not be obtained through deception or coercion.

Section 18(2) of PHIPA specifies that a Consent to the collection, use or disclosure of personal health information about an individual may be express or implied with exceptions.

Part IV of PHIPA defines the requirements for collection, use and disclosure of personal health information with or without Consent from the client. In general, a health information custodian shall not collect, use or disclose personal health information about an individual unless it has the individual's Consent under PHIPA (section 29 of PHIPA).

[4] The online version of PHIPA can be found at the e-laws website at the following url: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm. Note that the version of PHIPA cited in this document was current as of February 2011.

6. Appendix B: Consent Management in CPF

The Common Privacy Framework document describes key consideration in the requirements, design and implementation of the Consent management process. This section provides a copy of the key considerations presented in Common Privacy Framework for your reference.

6.1 Requirements

Consent Type

Informed Consent (either implied or express)

Consent can be either implied or express, but in order to be valid the Consent must be knowledgeable and for the purposes of this framework, informed. Knowledgeable Consent is defined under PHIPA (see appendix A for more details) as requiring the client to know:

(a) the purposes of the collection, use or disclosure, as the case may be; and

(b) that the individuals may give or withhold Consent.

In this framework, we defined informed Consent as knowledgeable Consent as well as:

- The client should be aware of the information that is collected, used and disclosed
- Clients should be aware of the positive and negative consequences of giving, withholding or withdrawing Consent
- The HSP must be reasonably certain that the Client understands the information provided to them
- The person is well informed enough to ask any clarifying questions, and has received responses to his or her requests for additional information

Example: The client may be informed verbally, in writing through posters or brochures or through any means deemed necessary for them to understand. Whether the client is asked directly to provide Consent or is not explicitly asked for their Consent to the collection, use and disclosure of their PHI is up to the HSP's discretion as long as the client is informed.

Scope of Consent Directives

Each HSP should determine the scope of Consent Directive that they are able to support. HSPs should communicate this with all clients so that clients can make informed decisions on Consent. At minimum, an HSP's Privacy policy and practice should support a client's Consent Directive applied to all of their PHI. HSPs are encouraged to explore ways of refining the scope of the Consent Directive.

Example: If an HSP's electronic health record software is not able to hide a specific section of the client's health records, then the HSP must inform the client that their Consent will be applied to the whole health record so their Consent will either be "share all" or "share nothing".

Consent Directive Override

Express Consent is required to override the Consent Directive.

Example: If the client has withdrawn their Consent and the client has been referred for treatment to another HSP, the HSP must expressly ask the client to see their PHI since the client previously withdrew their Consent. Their PHI cannot be assumed to be shared, even though a referral would normally include PHI.

Note: IAR does not currently support privacy override function.

Disclosure without Consent

As per PHIPA Section 40(1), "Health information custodians may disclose a patient's PHI without Consent where the custodian believes on reasonable grounds that the disclosure is necessary for the purpose of eliminating or reducing a significant risk of serious bodily harm to a person or group of persons", Clients should be informed that disclosures may occur in situations where the HSP staff believe that it is necessary to avoid serious bodily harm.

6.2 Design

The Consent management process is comprised of, but not limited to, three key activities:

Inform the Client

Regardless of whether the HSP uses implied or express Consent, the client must be informed of the purpose for the collection/use/disclosure of their PHI, as well as their Privacy rights. The HSP can take a different approach to inform the client depending on their business process, the client's preference, etc.

Obtain Consent

Once the client is informed of the purpose of PHI collection/use/disclosure and their Privacy rights, the HSP can use their existing Consent practices to assume implied Consent or obtain express Consent.

Manage Consent

The Consent must be properly documented for tracking purposes. Appropriate actions should be taken to ensure that the Consent is registered in an electronic system or recorded on physical media along with PHI. Examples of physical media might include hard copy documents, spreadsheets, lists, reports, etc.

Example: Maintaining a log book, or excel spreadsheet of when Consent was obtained or withdrawn will make maintaining traceability of Consent Directives across programs, paper files and software files easier.

6.3 Implementation

People

All staff must receive proper training on the Consent management process.

Partner HSPs must be informed of the changes to the Consent management process, should they occur or be required.

The public, including clients, must be informed of the HSP's Privacy practices, including the Consent process.

Process

The HSP's Consent management process must be integrated with the HSP's clinical and/or assessment process. When PHI is shared externally with other HSPs, Consent management processes must be established between organizations to ensure effective collaboration and cooperation occurs.

Example: If an HSP's standard Consent process is to inform clients verbally, the discussion should be integrated into the HSP's intake or assessment process.

Technology

If HSPs have current technology that registers and enforces the Consent Directive but uses a manual procedure to obtain express Consent, a process needs to be in place to ensure that the manual procedure aligns with the technology functions regarding Consent.

Example: When a client withdraws Consent and that Consent Directive is captured manually, there needs to be some way for the electronic system to register that the client does not want their information shared, and for the electronic system to enforce and not show that information to anyone.